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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,297	12/19/2000	Genevieve Hansen	S-30025D	5673

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

14

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,297

Applicant(s)

HANSEN, GENEVIEVE

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-41 is/are pending in the application.
- 4a) Of the above claim(s) 32-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 20-25 drawn to methods for transforming plants susceptible to AIN with a nucleotide of interest comprising manipulation a condition: and exposing, wherein manipulating comprises a heat shock treatment. classified in class 435, subclass 419.
 - II. Claims 26-31, drawn to methods for transforming plants susceptible to AIN with a nucleotide of interest comprising manipulation a condition, comprises exposing to a chemical inhibitor of AIN, class 435, subclass 419.
 - III. Claims 32, 33, 35, 37, and 38 drawn to (a) an antisense sequence classified in class 536, subclass 24.1, for example.
 - IV. Claims 32, 34, 35, 36, 37 and 38 drawn to (b) a coding sequence, classified in class 435, for example.
2. Inventions I, II, III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

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808.01). In the instant case the different inventions have different modes of operation, different functions, or different effects.

3. Claims 20, 39, 40, and 41 link(s) inventions I, II, III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 20, 39, 40, and 41. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Groups I and II are elected by original presentation.

5. Groups III and IV are non-elected.

Status of the Claims

6. The Office acknowledges receipt of Applicants Response; dated 20 December 2002, paper number 12.

7. Applicant has cancelled claims 1-19, and added new claims 20-41. Claims 20-41 are pending and are subject to the restriction requirement above. Claims 20-31 are examined in the instant action. Claims 32-41 are withdrawn as drawn to non-elected inventions.

8. This action is made FINAL necessitated by Applicant's amendment.

9. All rejections not addressed below have been withdrawn.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

11. The Office acknowledges receipt of Applicant's IDS, Paper No. 13, dated 4 March 2003. A signed copy is returned with this Office action.

Claim Rejections - 35 USC § 112-second

12. Claims 20-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

The rejection to "exposing" as unclear is extended to new claims 20-31. The term "exposing" should be amended to "contacting", as "exposing" could be in the same vicinity without being in contact. Claim 20 does not result in transformation as set forth in the preamble.

Applicant traverses, stating primarily (p. 8) that that "exposing" not used in a way that is contrary to its accepted meaning in the art.

Applicant's traversal has been considered and is unpersuasive because the claims are directed to a method of transforming a plant cell or tissue. Transformation requires contact, while "exposure" encompasses "contact", not other exposure would result in transformation. Thus it is unclear what other exposures are intended by Applicant.

In new claim 20, "to inhibit a programmed cell death or apoptotic necrosis mechanism" is unclear because whereas "inhibiting a mechanism" does not make scientific sense. While a process can be inhibited, a mechanism can not be inhibited.

In claims 22, 23, 24, and 25, "about" is indefinite because the metes and bounds of "about" are unclear.

Clarification and/or correction are required.

Claim Rejections - 35 USC112, first paragraph

13. Claims 20-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 20-31, "susceptible to Agrobacterium induce necrosis", "manipulating", "inhibit programmed cell death", "apoptotic necrosis" and "mechanism" are new matter, and are not supported by the specification as of the date of filing. Also, "wherein (a) occurs before, during, or after (b)" is new matter because the specification does not disclose all three combinations.

14. Claim 20-31 rejected under 35 U.S.C. 112, first paragraph, because specification, while being enabling for a method of transforming a plant susceptible to AIN with a nucleotide of interest comprising manipulation of a condition of a plant cell or tissue to inhibit a programmed cell death or apoptotic necrosis process capable of being induced by exposure to Agrobacterium, where the condition is a heat shock treatment at 42-48 degrees C for a duration of 4-8 minutes, and the heat shock treatment occurs before the exposure to Agrobacterium, does not reasonably provide enablement for: unspecified conditions which inhibit Agrobacterium induced necrosis (AIN), or the broad scope of inhibiting agents or inhibitors, "conditions which inhibit", "agent", "a nucleotide sequence", "ethylene inhibitors, ethylene synthesis inhibitors, gibberellin antagonists, and phosphatase inhibitors".

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 20 is drawn to a method of transforming a plant susceptible to AIN with a nucleotide of interest comprising (a) manipulation of a condition of a plant cell or tissue to inhibit a programmed cell death or apoptotic necrosis process capable of being induced by exposure to Agrobacterium; and (b) exposing the cell or tissue to Agrobacterium comprising a nucleotide sequence of interest, where (a) occurs before, during, or after (b). Applicant is reciting a method of transforming a plant susceptible to AIN by the method of manipulating the conditions of AIN so that AIN is inhibited.

This is circular reasoning and does not provide adequate guidance.
"Manipulate" teaches no specific guidance.

Applicant traverses, stating primarily that the teachings of the disclosure have at their core the discovery that Agrobacterium induces programmed cell death or apoptotic necrosis, or AIN. And Applicant further found that inhibition of AIN during Agrobacterium mediated transformation can enhance transformation effectiveness or

efficiency. That once Applicant discovered the source of the problem, a variety of solutions would become apparent to those of ordinary skill in the art .

Applicant's traversal has been considered and is unpersuasive because whereas the specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable*, and must be recited in the claims.

Applicant traverses, stating primarily that Applicant 's disclosure teaches far more than two conditions for inhibition of AIN: heat shock treatment and the use of AgNO₃ as an ethylene inhibitor (p. 12). That the disclosure provides clear and exact description of certain molecular and biochemical features of AIN.

Applicant's traversal has been considered and is unpersuasive because while the specification does discuss specific conditions, Applicant's arguments are not commensurate in scope with the claims. The claims are not drawn to the specific conditions.

Applicant traverses, stating primarily that Applicant teaches far more than simple the use of AgNO₃ as a chemical inhibitor. That Applicant's disclosure provides various examples of ethylene inhibitors, ethylene synthesis inhibitors, gibberellin antagonists and phosphatase inhibitors (p. 13).

Applicant's traversal has been considered and is unpersuasive because "ethylene inhibitors, ethylene synthesis inhibitors, gibberellin antagonists and phosphatase inhibitors" are not specific compounds, and no specific structure is given.

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"Ethylene inhibitors, ethylene synthesis inhibitors, gibberellin antagonists and phosphatase inhibitors" are not taught, rather this a listing and does not comprise adequate guidance.

Applicant traverses, stating primarily that the Office has not offered sufficient evidence to doubt Applicant's presumptively accurate disclosure, and that the specification must be taken as enabling.

Applicant's traversal has been considered and is unpersuasive because of evidence set forth in the previous office Action as well as the rebuttal above.

Accordingly the Office has met its burden.

Claim Rejections - 35 USC § 102(b)

15. Claims 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Key at al, US 5,447,858, issued 5 September 1995.

Key teaches a method for transforming a maize (col 3, lines 64-65) plant cell or tissue with Agrobacterium comprising a nucleotide of interest (col 7, lines 1-5) by manipulating heat shock treatment (col 5, lines 53-58) to inhibit a programmed cell death or apoptotic necrosis mechanism, where the heat shock duration is 10 minutes and where the heat shock temperature is 40 C (col 6, line 12) and 45 C (col 5, line 65). Key also teaches the manipulation occurring "before, during, or after" contact with the Agrobacterium.

The Office interprets 10 minutes to be "about 2 minutes to about 10 minutes", and "about 4 minutes to about 8 minutes" because of the lack of clarity of "about".

Accordingly, Key anticipates the claimed invention.

16. Claims 20, 26, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by De Block, M, et al, Plant Physiol, 1989, vol 91, 694-701.

De Block teaches a method of transforming plant tissue to inhibit a programmed cell death or apoptotic necrosis mechanism, and a method of making a fertile, transgenic plant (Figure 1, p 698, final paragraph p 698), by exposing the tissue to Agrobacterium transforming a plant cell or tissue with a gene of interest comprising exposing said plant cell wherein said Agrobacterium comprises a vector comprising said gene of interest (Abstract, p 694). De Block also teaches the ethylene inhibitor AgNO₃ (Abstract; p 695, 1st paragraph and Table II). De Block also teaches the manipulation occurring "before, during, or after" contact with the Agrobacterium.

Accordingly, De Block anticipates the claimed invention.

17. Claims 20, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryals, et. al., US 5,614,395, issued 25 March 1995.

Ryals teaches a method for transforming corn (col 2, lines 25-28 and col 3, lines 38-40) with *Agrobacterium* comprising a nucleotide of interest (col 2, line 3) to inhibit a programmed cell death or apoptotic necrosis mechanism by manipulating a chemical inhibitor of AIN where the chemical is abscisic acid (col 4, line 57), and where the chemical is salicylic acid (col 34, lines 44-52, and claim 6). Ryals also teaches the manipulation occurring "before, during, or after" contact with the *Agrobacterium*.

Accordingly, Ryals anticipates the claimed invention.

Claim Rejections - 35 USC § 103

Double Patenting

18. The nonstatutory double patenting rejection is extended to new claims 20-31. Fulfillment of requirements to overcome this rejection will be held in abeyance until allowable subject matter is indicated, per Applicant's request.

Remarks

19. No claim is allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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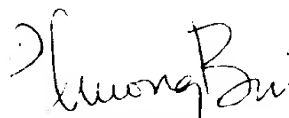
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner, art unit 1638
April 7, 2003


PHUONG T. BU
PRIMARY EXAMINER